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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS LTD., MERZ PHARMA GMBH & CO. KGAA, and MERZ PHARMACEUTICAL GMBH, Plaintiff, v. ORGENUS PHARMA INC., Defendants.	Civil Action No. 3:09-cv-05105 (MLC)(DEA) *ELECTRONICALLY FILED* **ANSWER OF ORGENUS PHARMA INC.** **COUNTERCLAIMS OF ORGENUS PHARMA INC.**

STATEMENT PURSUANT TO L.CIV.R. 10.1

Defendant Orgenus Pharma Inc. is a company organized and existing under the laws of New Jersey with its principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

ANSWER OF ORGENUS PHARMA INC.

Defendant Orgenus Pharma Inc. ("Orgenus") hereby answers the Complaint of Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Plaintiffs") and counterclaim as follows. Orgenus hereby denies all allegations not otherwise admitted or denied.

RESPONSE TO PARTIES[1]

1. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 of the Complaint and, therefore, denies the allegations of paragraph 1 on that basis.

2. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint and, therefore, denies the allegations of paragraph 2 on that basis.

3. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint and, therefore, denies the allegations of paragraph 3 on that basis.

4. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint and, therefore, denies the allegations of paragraph 4 on that basis.

5. Orgenus denies the allegations of paragraph 5 of the Complaint, except admits that Orgenus in a New Jersey corporation with a principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540 and that Orgenus is a subsidiary of Orchid Pharmaceuticals Inc., a Delaware corporation.

6. Orgenus denies the allegations of paragraph 6 of the Complaint.

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[1] To facilitate the Court's comparison of the allegations in the Complaint and defendants' responses thereto, Orgenus has incorporated modified Headings that appear in the Complaint. Orgenus does not necessarily agree with characterizations in such Headings and does not waive any rights to object to such characterizations or their implications.

RESPONSE TO NATURE OF THE ACTION

7. In responding to paragraph 7, Orgenus admits that the Complaint purports to state claims for infringement of United States Patent No. 5,061,703 ("the '703 patent"), which are based upon the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*., but Orgenus denies any liability or wrongdoing whatsoever.

RESPONSE TO JURISDICTION AND VENUE

8. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 8 of the Complaint, except admits that the District of New Jersey has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), but Orgenus denies any liability or wrongdoing whatsoever.

9. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 9 of the Complaint, except admits that for purposes of this action only that it is subject to personal jurisdiction in the District of New Jersey.

10. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 10 of the Complaint.

11. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 11 of the Complaint, except admits that for purposes of this action only that venue is proper in the District of New Jersey.

RESPONSE TO THE PATENT-IN-SUIT

12. Orgenus admits that United States Patent No. 5,061,703, titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," states on its face that it was issued October 29, 1991 by the United States Patent and Trademark Office. Orgenus denies that the '703 patent was "duly and legally issued" by the United States Patent and Trademark Office. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 12 of the Complaint and, therefore, denies them on that basis.

13. Orgenus admits that the '703 patent is listed in the Orange Book for Namenda®, but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 of the Complaint and, therefore, denies them on that basis.

14. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 of the Complaint and, therefore, denies the allegations of paragraph 14 on that basis.

15. Orgenus admits that an ex parte reexamination certificate for the '703 patent indicates on its face that it was issued by PTO on November 7, 2006. Orgenus lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 15 of the Complaint and, therefore, denies the remaining allegations of paragraph 15 on that basis.

RESPONSE TO ALLEGED ACTS GIVING RISE TO THIS ACTION

Alleged Infringement of the '703 Patent by Defendant Orgenus

16. Orgenus admits that Orchid Chemicals & Pharmaceuticals Ltd. submitted ANDA No. 90-044 to FDA seeking approval to market a 5 milligram and 10 milligram memantine hydrochloride tablet product prior to the expiration of the '703 patent and otherwise denies the allegations of paragraph 16 of the Complaint.

17. Orgenus admits that, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Orchid Chemicals & Pharmaceuticals Ltd. indicated in ANDA No. 90-044 its contention that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Orchid Generic Products and that Plaintiffs received written notification of ANDA No. 90-044 and its § 505(j)(2)(A)(vii)(IV) certification on or about December 10, 2007, but otherwise denies the allegations of paragraph 17 of the Complaint.

18. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 18 of the Complaint.

19. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 19 of the Complaint.

20. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 20 of the Complaint.

21. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 21 of the Complaint.

22. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 22 of the Complaint.

23. Orgenus denies each and every allegation and/or legal conclusion contained in paragraph 23 of the Complaint.

RESPONSE TO PRAYER FOR RELIEF

24. Orgenus repeats and realleges its responses to the allegations in paragraphs 1 through 23 of the Complaint as though fully set forth herein. The "WHEREFORE" paragraphs following paragraph 23 of the Complaint state Plaintiffs' prayer for relief for which no response is required. To the extent a response is required, Orgenus denies the allegations set forth in the "WHEREFORE" paragraphs and denies that Plaintiffs are entitled to any of the relief requested therein, or to any relief whatsoever.

DEFENSES

First Defense

(Non-infringement)

25. Orgenus repeats and realleges its responses to the allegations in paragraphs 1 through 24 of the Complaint as though fully set forth herein.

26. Orgenus does not infringe, has not infringed, and will not infringe (directly, indirectly, contributorily or by inducement) any valid and enforceable claim of the '703 patent.

Second Defense

(Invalidity)

27. Orgenus repeats and realleges its responses to the allegations in paragraphs 1 through 26 of the Complaint as though fully set forth herein.

28. Upon information and belief, each and every claim of the '703 patent is invalid and void for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, 132, and 305.

Third Defense

(Invalidity of PTE)

29. Orgenus repeats and realleges its responses to the allegations in paragraphs 1 through 28 of the Complaint as though fully set forth herein.

30. Upon information and belief, the patent term extension for the '703 patent is invalid due to a material failure to comply with the requirements of 35 U.S.C. § 156.

COUNTERCLAIMS

Defendant/Counterclaimant Orgenus Pharma Inc. ("Counterclaimant") brings the following Counterclaims against Plaintiffs/Counterdefendants Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively "Counterdefendants").

The Parties

1. Orgenus Pharma Inc. ("Orgenus") is a company organized and existing under the laws of New Jersey with its principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540.

2. Upon information and belief, Counterdefendant Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

3. Upon information and belief, Counterdefendant Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

4. Upon information and belief, Counterdefendant Merz Pharma GmbH & Co. KGaA is a German corporation having a principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany.

5. Upon information and belief, Counterdefendant Merz Pharmaceuticals GmbH is a German corporation having a principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany (referred to herein, together with Merz Pharma GmbH & Co. KGaA, as "Merz").

6. Upon information and belief, Merz is the owner of United States Patent No. 5,061,703 ("the '703 patent"), titled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," a copy of which is attached to Counterdefendants' Complaint as Exhibit A.

7. Upon information and belief, Forest asserts that it is the exclusive licensee of the '703 patent in the United States and Forest holds New Drug Application ("NDA") No. 21-487 for Namenda brand memantine hydrochloride tablets.

Nature of the Action

8. This is an action for a declaration of patent noninfringement, invalidity and patent de-listing arising under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction And Venue

9. This Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Upon information and belief, this Court has jurisdiction over Counterdefendants.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(d), as well as Counterdefendants' motion to transfer this case to this judicial district.

12. Counterdefendants have created an actual controversy between themselves and Orgenus through listing of the '703 patent in the Orange Book, as well as by virtue of its allegations that Orgenus's submission of ANDA No. 90-044 to FDA constituted an act of infringement under 35 U.S.C. § 271(e) with regard to one or more claims of the '703 patent.

The Patents and Related Drug Product

13. Pursuant to 21 U.S.C. § 355(j), the Federal Food, Drug and Cosmetic Act ("FDCA") authorizes a generic drug company to file an ANDA with FDA for approval of a generic drug product that has the same active ingredient as, and is bioequivalent to, a drug product that FDA has already approved pursuant to an NDA.

14. Pursuant to 21 U.S.C. § 355(b), the FDCA requires NDA holders to submit to FDA the patent numbers and expiration dates of any patent that claims the drug or a method of using the drug for which an NDA is filed. FDA then lists those patents in The Orange Book.

15. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), if a generic drug company seeks approval to market a generic drug product prior to the expiration of a patent listed in the Orange

Book, the generic drug company is required by law to include a certification in its ANDA that the patent is invalid, unenforceable, or will not be infringed by the generic drug product ("Paragraph IV Certification").

16. Pursuant to 21 U.S.C. § 355(j)(2)(B), if the generic drug company includes a Paragraph IV Certification in its ANDA, the generic drug company must send the NDA holder and the patent owner notice of that certification, including a detailed statement of the factual and legal basis for the generic drug company's opinion that the patent is invalid, unenforceable or will not be infringed ("Notice Letter").

17. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), if a suit for patent infringement is brought within 45 days of receiving the Notice Letter, FDA generally may not grant final approval for the generic drug company's ANDA for 30 months or until resolution of the patent infringement action.

18. On information and belief, Forest is the holder of NDA No. 21-487 for memantine hydrochloride tablets. On information and belief, the trade name of Forest's memantine hydrochloride tablet product is Namenda.

19. On information and belief, Forest requested that FDA list the '703 patent in The Orange Book for Namenda, NDA No. 21-487.

20. Orchid Chemicals & Pharmaceuticals Ltd. filed ANDA No. 90-044 with FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the memantine hydrochloride tablet product described in its ANDA prior to the expiration of the '703 patent. Orchid Chemicals & Pharmaceuticals Ltd. included in ANDA No. 90-044 a Paragraph IV Certification stating that, in the opinion of Orchid Chemicals & Pharmaceuticals Ltd., and to the best of its knowledge, the '703 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the memantine hydrochloride tablet product described in its ANDA.

21. By letter dated December 7, 2007, Orchid Chemicals & Pharmaceuticals Ltd. sent Counterdefendants a Notice Letter that included a detailed statement of the factual and legal

basis for Orchid's opinion that its memantine ANDA product would not infringe any valid and enforceable claim of the '703 patent. Pursuant to 21 U.S.C. § 355(j)(5)(C), the Notice Letter was accompanied by an Offer of Confidential Access to ANDA No. 90-044. On or about December 10, 2007, Counterdefendants received the Notice Letter.

22. On or about May 16, 2008, Counterdefendants filed a Complaint in the District of Delaware against Orgenus Pharma Inc. alleging infringement of the '703 patent. Counterdefendants asserted in their Complaint that the filing of ANDA No. 90-044 was an act of infringement of the '703 patent under 35 U.S.C. § 271(e)(2). Counterdefendants also asserted in their Complaint that the commercial manufacture, use, offer for sale, sale, or importation of the product described in ANDA No. 90-044 would infringe one or more claims of the '703 patent under 35 U.S.C. § 271.

23. Counterdefendants' assertion against Orgenus of claims of infringement of the '703 patent after being advised by Orchid Chemicals & Pharmaceuticals Ltd. in its Notice Letter that there is no basis for those claims renders the Counterclaimant's case exceptional within the meaning of 35 U.S.C. § 285.

24. Orgenus has no adequate remedy at law. The actions and assertions made by Counterdefendants with respect to the '703 patent have caused and will continue to cause irreparable injury to the rights of Orgenus.

First Counterclaim

(Declaratory Judgment Of Non-infringement)

25. Orgenus repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

26. Orgenus has not infringed any claim of the '703 patent related to Orchid Chemicals & Pharmaceuticals' filing ANDA No. 90-044, and the commercial manufacture, use, importation, offer for sale and/or sale of the product described in ANDA No. 90-044 will not infringe any valid and enforceable claim of the '703 patent.

27. Because Orgenus has not infringed and will not infringe any claim of the '703 patent, Plaintiffs and Counterdefendants are not entitled to damages or any other relief from or against Orgenus.

Second Counterclaim

(Declaratory Judgment Of Invalidity)

28. Orgenus repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

29. Each and every claim of the '703 patent is invalid and void for failure to meet the requirements of Title 35, United States Code, including, *inter alia*, §§ 101, 102, 103, 112, 132, and 305.

Third Counterclaim

(Order To Delist The '703 Patent from The Orange Book)

30. Orgenus repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

31. Forest's NDA No. 21-487 for Namenda® brand memantine hydrochloride tablets is approved by the Food and Drug Administration ("FDA") for the treatment of moderate to severe dementia of the Alzheimer's type.

32. The '703 patent does not claim the use of memantine in a method for the treatment of moderate to severe dementia of the Alzheimer's type and, therefore, does not claim an approved method of using memantine hydrochloride.

33. Pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I)(bb), Orgenus is entitled to an Order requiring Counterdefendants to remove the '703 patent from the Orange Book for NDA No. 21-487.

PRAYER FOR RELIEF

WHEREFORE, Orgenus Pharma Inc. respectfully requests this Court enter a Judgment and Order:

A. dismissing the Complaint, and each and every Claim for Relief contained therein, with prejudice;

B. an Order requiring Counterdefendants to remove the '703 patent from the Orange Book for NDA No. 21-487;

C. declaring that no valid and enforceable claim of United States Patent No. 5,061,703 has been or would be infringed (either directly, indirectly, contributorily or by inducement) by Orgenus;

D. declaring the claims of United States Patent No. 5,061,703 invalid;

E. declaring this case exceptional pursuant to 35 U.S.C. § 285 and awarding Orgenus its attorneys' fees, costs and expenses; and

F. granting such other and further relief as this Court may deem just and proper.

Dated: October 14, 2009

s/ Jason B. Lattimore

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that to the best of my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ Jason B. Lattimore
Jason B. Lattimore

Dated: October 14, 2009